SUMMARY OF SAFETY AND EFFECTIVENESS DATA

December 14, 2000

Submitted By: NuMED, Inc., 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: MultiTrack Angiographic Catheter

Predicate Devices: MAP MultiTrack Angiographic Catheter

Device Description: The MultiTrack Angiographic catheter is a single lumen catheter used in catheterization for angiography of cardiovascular vessels and/or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel. The catheter shaft is constructed of radiopaque compounded plasticized nylon tubing, blue in color, and features a molded proximal end used for injection of contrast medium through a closed-end distal tip which has 4 side-holes. The distal 1cm of the catheter tip is offset and designed to accept a guidewire. A platinum iridium image band is imbedded 2mm from the distal tip as an aid to enhance visualization under fluoroscopy.

Biocompatibility Testing:

The materials used in the MultiTrack Angiographic Catheter are the same as those used in our PTA Catheters (510(k) #K931009) and PTV Catheters (510(k) #K991977), which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.
Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

Intended Use: Recommended for use in catheterization for angiography of cardiovascular vessels and/or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel.

Comparison Information

MODEL:	MAP MULTITRACK ANGIOGRAPHIC	MULTITRACK ANGIOGRAPHIC
Indications:	Recommended for use in catheterization for angiography of cardiovascular vessels and/or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel.	Recommended for use in catheterization for angiography of cardiovascular vessels and/or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel.
Introducer:	6Fr – 7Fr	4Fr – 8Fr
Shaft Size:	4Fr – 5Fr	2.5Fr, 3Fr-6Fr
Guidewire Size:	0.035"	0.021", 0.025", 0.035"
Usable Length:	100cm	60, 80, 100cm
Rated Burst Pressure:	1000psi	1000psi
Flow Rate:	4Fr – 9.6cc/sec 5Fr – 15.36 cc/sec	2.5Fr – 60cm – 3.5cc/sec 2.5Fr – 80cm – 2.7cc/sec 3Fr – 60cm – 6.5cc/sec 3Fr – 80cm – 5.5cc/sec 3Fr – 100cm – 4.0cc/sec 4Fr – 80cm – 13.0 cc/sec 4Fr – 100cm – 11.0cc/sec 5Fr – 80cm – 22.0cc/sec 5Fr – 100cm – 20.0cc/sec 6Fr – 100cm – 25.0cc/sec
Materials:	Shaft: PES2 Image Band: Platinum	Shaft: PES2 Image Band: Platinum
Construction:	Single lumen catheter with side holes at the tip and a 1cm section at the distal tip for catheter tracking. The tubing is radiopaque for proper visualization under fluoroscopy.	Single lumen catheter with side holes at the tip and a 1cm section at the distal tip for catheter tracking. The tubing is radiopaque for proper visualization under fluoroscopy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Ms. Nichelle R. LaFlesh
Regulatory Affairs Manager
NuMed, Inc.
P.O. Box 129
Nicholville, NY 12965

Re: K003902
Trade Name: MultiTrack Angiographic Catheter
Regulatory Class: II
Product Code: DQO
Dated: December 18, 2000
Received: December 19, 2000

Dear Ms. LaFlesh:

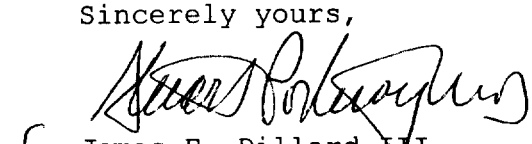
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K003902

Device Name: **MultiTrack Angiographic Catheter**

Indications For Use:

Recommended for use in catheterization for angiography of cardiovascular vessels and/or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE ~~IF NEEDED~~)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003902

1-11-1

(Optional Format 1-2-96)